PTO/SB/64 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)	Docket Number (Optional) **P-71486-US2**

First named inventor: **KILCOYNE, John T et al.**

Application No.: **10/687,336** Group Art Unit: **3736**

Filed: **October 16, 2003** Examiner: **NGUYEN, Huong Q.**

Title: **IMPLANTABLE MONITORING PROBE**

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703)305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus an extension of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee - - required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. Petition fee

☐ Small entity - fee $ _____ (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.

☒ Other than small entity - fee $ **1,620.00** (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of **Amendment in Response to final Office action** (identify type of reply):

☐ has been filed previously on _____.

☒ is enclosed herewith.

B. The issue fee of $ _____

☐ has been paid previously on _____.

☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____ for a small entity or $ _____ for other than a small entity) disclaiming a period equivalent to the period of abandonment is enclosed herewith (see PTO/SB/63).

4. Statement. The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE. The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c)(III)(C) and (D)))].

5. ☒ Please charge my Deposit Account No. **50-3355** in the amount of $**1,620.00** to cover the above fees.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **50-3355**.

10 March, 2010
Date

/Guy Yonay/
Signature

Telephone Number: (**646**) **878-0800**

Guy Yonay 52,388
Typed or printed name

Customer No. 49443
Pearl Cohen Zedek Latzer, LLP
1500 Broadway, 12th Floor
New York, New York 10036

Enclosures:
☒ Fee Payment
☒ Reply
☐ Terminal Disclaimer Form
☐ Small Entity Status Form
☐ Additional sheets containing statements establishing unintentional delay
☒ **Request for Continued Examination (RCE) Transmittal**

Attorney Docket No.: P-71486-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	KILCOYNE, John T., et al.	Examiner:	NGUYEN, Huong Q.
Serial No.:	10/687,336	Group Art Unit:	3736
Filed:	October 16, 2003	Confirmation No.:	7853
Title:	IMPLANTABLE MONITORING PROBE		

AMENDMENT

Mail Stop RCE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amendment is being filed in response to the final Office action dated June 11, 2009 issued by the United States Patent and Trademark Office in connection with the above-identified Application. A response was due September 11, 2009; however, Applicants did not receive the Office action. A petition to revive an unintentionally abandoned application is being filed concurrently herewith, together with the required fee. A request for continued examination is also being filed herewith, together with the required fee. Accordingly, this amendment is timely filed.

Kindly amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page **2** of this paper.

Remarks/Arguments begin on page **5** of this paper.

AMENDMENTS TO THE CLAIMS

Please add or amend the claims to read as follows, and cancel without prejudice or disclaimer to resubmission in a divisional or continuation application claims indicated as cancelled:

1-49. (Canceled)

50. (**Currently amended**) A system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising:

a monitoring device, said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body and a plurality of sensors included in said housing ~~adapted to be implanted in the body of a patient~~, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux ~~different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors~~ and wherein said monitoring device ~~each of the plurality of sensors~~ periodically transmits a signal indicative of the value of the respective ~~measured~~ physiological parameter measured by each of the plurality of sensors ~~that is indicative of gastroesophageal reflux and wherein each of the signals includes an identifier that is indicative of the sensor from which the signal is sent~~; and

a receiver that receives the signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, ~~determines a location for each sensor within an esophagus based on the identifier~~, [[and]] monitors the physiological parameters indicative of gastroesophageal reflux based on the received signals, and determines at least the presence of gastroesophageal reflux based on said plurality of signals ~~the determined locations~~.

51. (**Currently Amended**) The system of Claim 50, wherein at least one of said ~~each of the~~ plurality of sensors includes a pH monitor ~~and an RF transmitter~~.

52. (**Currently Amended**) The system of Claim 51, wherein said monitoring device further ~~each of the plurality of sensors also~~ includes a radio frequency (RF) transmitter and a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor.

53. (**Currently Amended**) The system of Claim 52, wherein the microprocessor ~~of each of the sensors~~ periodically enables the pH monitor of the monitoring device ~~respective sensor~~ during a first interval of each measurement cycle to obtain the pH signal and then disables the pH monitor during a second interval.

54. (**Currently Amended**) The system of Claim 53, wherein the microprocessor ~~of each of the sensors~~ enables the RF transmitter ~~of the respective sensor~~ during the second interval and disables the RF transmitter during periods of each cycle other than the second interval and disables the pH monitor ~~of the respective sensor~~ during periods of each cycle other than the first interval.

55. (**Currently Amended**) The system of Claim 50, wherein each of the signals includes an identifier that is indicative of the monitoring device from which the signal is sent and wherein the identifier for each of the signals comprises at least one of a frequency or a code.

56. (Previously Presented) The system of Claim 50, wherein the receiver is configured to be worn by the patient.

57. (Previously Presented) The system of Claim 50, wherein the receiver includes circuitry to sense a position of the patient, and the receiver periodically records the position of the patient.

58. (Previously Presented) The system of Claim 50, wherein the receiver monitors a change in pH as a function of distance from a lower esophageal sphincter.

59. (**New**) The system of Claim 50, wherein said plurality of sensors include a pH monitor and an auxiliary sensor, wherein said auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, wherein the receiver is configured to receive a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter.

60. (**New**) The system of Claim 59, wherein the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure.

REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims **50-60** are pending in the application.

Claims **50-58** have been rejected.

Claims **50-55** have been amended in this submission.

Claims **59** and **60** are newly added in this submission.

Support for New and Amended Claims

Support for the new and amended claims may be found throughout the specification of the present application, including at paragraphs [0063]-[0064] of the application as published, reproduced below:

> [0063] FIG. 2 illustrates a simplified circuit for a monitor 18 of a physiological parameter (hereinafter "monitor 18"). This monitor 18 may also be referred to as a "probe"or "pill". In the particular embodiment illustrated in FIG. 2, pH is the physiological parameter to be sensed, and it is detected by a transducer 110, which comprises a pH sensor and preferably also a reference sensor. In the present invention, a monitoring transducer (hereinafter "transduced") can be any transducer that senses a physiological parameter and furnishes a signal one of whose electrical characteristics, such as current or voltage, is proportional to the measured physiological parameter.
>
> [0064] Although a pH sensor is described here those skilled in the art will appreciate that a sensor of any of a variety of other physiological

> parameters, such as pressure or temperature, can be detected and monitored. Sometimes, temperature and/or pressure will be sensed and transduced together with pH, in order to adjust the pH readings and make them more accurate, or to supply additional data helpful in the analysis of the patient's condition. In addition, the concentration of ions or other solutes present in body fluids can be detected and analyzed using this invention. For example, ions such as sodium, potassium, calcium, magnesium, chloride, bicarbonate, or phosphate may be measured. Other solutes whose concentrations in body fluids are of importance and may be measured by the present invention include, among others, glucose, bilimbin (total, conjugated, or unconjugated), creatinine, blood urea nitrogen, urinary nitrogen, renin, and angiotensin. Any combination of two or more of the preceding parameters may be sensed by the transducer 110. For any physiological parameter sensed and transduced by means of a transducer, a reference sensor may or may not be required.

Accordingly, Applicants respectfully assert that all pending claims are supported by the written description of the present application.

CLAIM REJECTIONS

35 U.S.C. § 112 Rejections

In the final Office action, the Examiner rejected claims 50-58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description specification. Specifically, the Examiner stated that it does not appear that Applicants' disclosure provides support for "[each of] the plurality of sensors is capable of independently measuring a physiological parameter indicative of gastroesophageal reflux different from other physiological parameters indicative of gastroesophageal reflux measured independently by other sensors" as recited by independent claim 50. In light of the amendments to claim 50, it is respectfully submitted that the rejection is moot.

The Examiner stated that it is unclear what is meant by "other sensors" and thus in the rejection it was assumed that the "other sensors" are external sensors. In light of the amendments to claim 50, it is respectfully submitted that the rejection is moot.

35 U.S.C. § 103 Rejections

In the Office action, the Examiner rejected claims 50-51, 55 and 58 under 35 U.S.C. § 103(a), as being unpatentable over Stuebe et al. (US Patent No. 5,117,827) in view of Reichstein (US Patent No. 4,632,119), further in view of Steffel et al. (US Patent No. 4,326,535), and even further in view of Ishikawa et al. (US Patent No. 6,398,710). Applicants traverse the rejection for at least the reasons that follow.

First, none of the Stuebe, Reichstein and Steffel references teach or suggest an implantable sensor. As clearly shown in Stuebe (Fig. 6A, item 23), Reichstein (Fig. 2, item 16), and Steffel (Fig. 1, item 16), these references do not teach or suggest a housing or sensors adapted to be implanted in the body of a patient. Rather, as taught by Stuebe, Reichstein and Steffel, a catheter or other means to which a sensor is coupled are used in order to position and keep the sensor at a specific location.

In contrast, according to the present application, cumbersome means such as a catheter are avoided, and the claims recite an implantable housing including sensors:

> Thus, there remains a need for an ambulatory system that avoids the use of an indwelling nasoesophageal catheter during the assessment of esophageal pH and other physiological parameters to detect gastroesophageal reflux. (Application as published, para. [0014], emphasis added).

This feature of the pending claims is neither disclosed nor obvious based on the cited references. The Examiner's citation of the Ishikawa reference is further unavailing. The Ishikawa references discloses a "radiation dosimetry system using miniature implanted transponder balls" (Abstract). The Ishikawa reference does not disclose a pH sensor, or any sensor, for that matter. The Ishikawa reference in fact bears no relation whatsoever to the Stuebe, Reichstein and Steffel references, and there would have been no reason for one of ordinary skill in the art of in vivo sensing to look to a radiation dosimetry system to solve any particular problem. Therefore, the Examiner's rejection based on Stuebe, Reichstein and Steffel in combination with the Ishikawa reference is improper.

In addition, the cited references do not disclose "a plurality of sensors. . ., wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux and wherein said monitoring

device periodically transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors," as recited in claim 50 as amended.

Accordingly, claim 50, and claims 51-60, which depend therefrom, are allowable over the cited references.

In addition to the above discussion of claim 50, newly added claims 59 and 60 are not disclosed or obvious in view of the cited references.

Claim 59 recites that the plurality of sensors include a pH monitor and an auxiliary sensor, wherein the auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, wherein the receiver is configured to receive a pH reading from the pH sensor and to adjust the pH reading based on the measured value of the physiological parameter.

Claim 60 recites that the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure.

In view of the foregoing amendments and remarks, the pending claims 50-60 are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

/Guy Yonay/
Guy Yonay
Attorney/Agent for Applicants
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Dated: March 10, 2010

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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995.
See The American Inventors Protection Act of 1999 (AIPA)

Application Number	**10/687,336**
Filing Date	**October 16, 2003**
First Named Inventor	**KILCOYNE, John T**
Group Art Unit	**3736**
Examiner Name	**NGUYEN, Huong Q.**
Attorney Docket Number	**P-71486-US2**

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: *37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Final Rule, 65 Fed. Reg. 50092 (Aug 16, 2000);* Interim Rule, 65 *Fed. Reg.* 14865 (Mar 20, 2000), *1233 Off. Gax. Pat. Office* 47 (Apr. 11, 20000), *which established* RCE *practice.*

1. Submission required under 37 C.F.R. § 1.114
   - a. ☐ Previously submitted
     - i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on (Any unentered amendment(s) referred to above will be entered).
     - ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on
     - iii. ☐ Other _____
   - b. ☒ Enclosed
     - i. ☒ Amendment/Reply
     - ii. ☐ Affidavit(s)/Declaration(s)
     - iii. ☐ Information Disclosure Statement (IDS)
     - iv. ☒ Other Petition for Revival of an Application for Patent Abandoned Unintentionally under 37 CFR 1.137(b)
2. Miscellaneous
   - a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. §.17(i) required)
   - b. ☐ Other _____
3. Fees — The RCE fee under 37 C.F.R. § 1.17 (D) is required by 37 C.F.R. § 1.114 when the RCE is filed.
   - a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. **50-3355**.
     - i. ☒ RCE fee required under 37 C.F.R. § 1.17(e)
     - ii. ☐ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
     - iii. ☒ Other Petition Fee required under 37 C.F.R. § 1.17(m)
   - b. ☐ Check in the amount of $_____ enclosed
   - c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	**Guy Yonay**	*Registration No. (Attorney/Agent)*	**52,388**
Signature	/Guy Yonay/	*Date*	**March 10, 2010**

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Assistant Commissioner for Patents, Washington, DC 20231.